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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,992	03/15/2004	Gary J. Beck	D-2804CON2	2049

7590 07/05/2005

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EXAMINER
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JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/800,992

Applicant(s)

BECK ET AL.

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/15/04 & 6/14/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The preliminary amendment filed 15 March 2004 has been received and entered. Claims 1-30 have been canceled. **Claims 31-50 are presented for examination.**

#### ***Information Disclosure Statement***

The information disclosure statements filed on 15 March 2004 and 14 June 2004 have been reviewed and considered. In the IDS submitted on 15 March 2004, the prior art document titled "Methods of Investigating and Preparing Inclusion Compounds, Cyclodextrins and their Industrial Uses" has been crossed out because it does not have a date. The Japanese documents have been crossed out because they do not have a date and the Australian Convention Application of Patent Application No 62-140730 has been crossed out because it does not have a date. See enclosed copy of PTO FORM 1449.

#### ***Specification***

The disclosure is objected to because of the following informalities: page 13 is missing.

Appropriate correction is required.

### ***Claim Objections***

Claim 32 is objected to because of the following informalities: the word "predonisolone" is misspelled. The correct spelling is "prednisolone". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 32, the phrase "apparent solubility" in line 3 of the claim renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "apparent solubility"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). It is not understood what is meant by "apparent solubility". Is it the solubility of the prednisolone acetate or is it some unknown value that has not been disclosed?

Claim 42 is indefinite to the extent that it reads on the rejected base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-36, 39-46 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Loftsson U.S. 5,481,954 A.

Loftsson et al. teach an ophthalmic composition (column 18, lines 8-12) comprising a cyclodextrin, such as the sulfobutyl ether of  $\beta$  cyclodextrin (column 6, line 60) and an anti-inflammatory steroid (column 19, lines 16-39), such as prednisolone (see table 10, column 28). The ophthalmic cyclodextrin composition has water added in addition to the active ingredient along with pH adjusters, buffers and preservatives, in a sterile isotonic buffered aqueous solution (column 19, lines 24-31).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31, 36-38, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftsson as applied to claims 31-36, 39-46 and 49-50 above, and further in view of Dziabo et al. U.S. Patent No. 5,424,078.

Claims 37-38 are drawn to a cyclodextrin and prednisolone composition preserved with a chlorite preservative such as chloride dioxide. Loftsson et al., as disclosed above, teach a preserved cyclodextrin and prednisolone ophthalmic composition lacking the chlorite preservative.

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Dziabo et al. teach an ophthalmic composition with a stabilized chloride dioxide preservative (see abstract).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ chloride dioxide as a preservative in an ophthalmic preparation motivated by the teaching of Dziabo et al who employs stabilized chlorine dioxide as a preservative for ophthalmic preparations.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe  
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Art Unit 1614

06/27/2005

  
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